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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/715,891 | 11/17/2000 | Susan R. Webb | TSRI 536.1Div2 | 7205 |

7590 12/04/2003

The Scripps Research Institute
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| EXAMINER |
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VANDERVEGT, FRANCOIS P

| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 09/715,891 | Applicant(s) WEBB ET AL. | |
| | Examiner F. Pierre VanderVegt | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a divisional of U.S. Application Serial Number 09/194,285, which is a rule 371 continuation of application serial number PCT/US97/08697, which claims priority to provisional application 60/018,175.

Applicant should amend the priority data on page 1 of the specification in order to display the relationship to the PCT application, as the provisional application lapsed prior to the filing of the '285 application.

Claims 1-60 and 83-148 have been canceled.

Claims 61-82 are currently pending in this application and are the subject of examination in the present Office Action.

1. Upon review, all prior grounds of rejection have been withdrawn and replaced by the following grounds of rejection. As the new grounds of rejection were not necessitated by Applicant's amendment, this action is made NON-FINAL.

Applicant's arguments filed October 14, 2003 with respect to claims 61-82 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 61-71, 73, 75 and 77-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for accessory molecules selected from the costimulatory molecules B7.1 and B7.2, the adhesion molecules ICAM-1, ICAM-2, ICAM-3 and LFA-3 and the survival molecules Fas ligand and CD70, does not reasonably provide enablement for any and all types of accessory molecule. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are most broadly drawn to the construction of a "poikilothermic synthetic antigen presenting cell" (APC) comprising an intact Class II MHC molecule and an "accessory molecule." The instant specification discloses the accessory molecules B7.1, B7.2 (costimulatory molecules), ICAM-1, ICAM-2, ICAM-3, LFA-3 (adhesion molecules), Fas ligand and CD70 (survival molecules). Beyond the disclosed elements, the term "accessory molecule" encompasses any molecule which may participate in the processes of antigen processing and/or presentation, including all molecules which have a role from capture and uptake of an antigenic molecule by an APC to internal molecules which chaperone the antigen or break up larger proteins into epitope peptides, molecules which assist the association of the epitope with the Class II molecule and cytokines which stimulate the activation of reactive T cells, as all such molecules perform accessory functions to MHC class II. The specification does not teach molecules which participate in all aspects of antigen processing and presentation and therefore does not provide sufficient guidance to one of ordinary skill in the art to practice the claimed invention commensurate in scope with the recitation of "accessory molecules."

In view of the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

3. Claims 61-67 and 70-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth insect cells that have been transformed to express MHC class II heterodimers and accessory molecules. The term "poikilothermic synthetic antigen presenting cell" in the claims broadly encompasses any type of cell derived from an organism having a body temperature that varies with the temperature of its surroundings, including such ectotherms as fish or reptiles. Applicant has not disclosed other cell types that would be suitable for use in making the claimed synthetic APCs, only stating that insect cells are particularly well suited for use (page 8, lines 4-13 for example). The instant specification does not describe other cell types, nor are vectors suitable for the transformation of non-insect cell types described.

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Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Accordingly, the written description in this case only sets forth insect cells as the source cell lacking any one of the components of the MHC class II heterodimer or an accessory molecule for the manufacture of synthetic APCs.

4. Claims 61-67 and 70-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using synthetic MHC class II positive antigen presenting cells via transfection of insect cells, does not reasonably provide enablement for utilizing cells from other poikilothermic organisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Briefly, the claims are most broadly drawn to the making and using of a "eukaryotic poikilothermic synthetic antigen presenting cell" (APC) which can present antigen in the context of MHC class II. The claim therefore reads upon any cell that is derived from an organism having a body temperature that varies with the temperature of its surroundings. The breadth of the claim therefore encompasses cells from ectothermic animal sources as diverse as reptiles, fish, echinoderms, mollusks and nematodes, for example. The instant specification exemplifies cells and vectors representative of insect species, more specifically, *Drosophila melanogaster*. The instant specification provides guidance by which the artisan can transfect insect cells with the MHC subunits and the accessory molecules and express said molecules on the surface of the insect cell. However, the specification is not enabling for the transfection and use of other types of cells. There is no disclosure of vectors which are suitable for transfection of other cell types, nor is there a disclosure of culture conditions, such as media supplements required, for the propagation and maintenance of non-insect poikilothermic cells. It would require an undue amount of experimentation on the part of the artisan to devise expression vectors and establish culture conditions for cells from other types of organisms, such as echinoderms, which would be conducive for the expression of MHC class II heterodimers and requisite accessory molecules on the cell surface for that cell to effectively function as an effective APC.

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In view of the nature of the invention, quantity of experimentation necessary, the limited working examples, the state and unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Conclusion

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Effective January 8, 2004, the Examiner's telephone number will be (571) 272-0852.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
November 24, 2003

Pat J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
12/1/03